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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,483	09/10/2003	Dale Julian Mischynski	40851-P001C1	3420

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT PAPER NUMBER

3762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/659,483

Applicant(s)

MISCZYNSKI ET AL.

Examiner

George R. Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 19, 21, 22, 24, 26-30, 34-41 and 53-73 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 19, 21, 22, 24, 26-30 and 34-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53-60 and 71-73 is/are rejected.
- 7) ☒ Claim(s) 54-70 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/10/03</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 1-3, 19, 21, 22, 24, 26-30, and 34-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/30/06.

### ***Claim Objections***

Claims 54-70 are objected to because of the following informalities listed below. Appropriate correction is required.

In claim 54, lines 6 and 7, "the" should be "a" since the parameters have not been previously discussed. In the last line, "of significant R-R intervals" first needs to set forth that the significant R-R intervals have been determined before it can be used in the claim. It is suggested to insert "determining significant R-R intervals" before the averaging step.

In claim 55, lines 11 and 13, "said" or "the" should be inserted before "QRS" since the QRS fragment has previously been discussed.

In claim 56, line 3, "a" should be inserted before "current" and in the last line, "said" should be inserted before "current", "noise" and "threshold".

In claim 60, "extracting R point" needs to be clarified since claim 55 has not set forth an extraction of R points.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 53 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Skinner (5709214).

Claim 53 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ambos et al (4680708).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 54 and 56 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ambos et al. Ambos states in column 4 that the current R-R interval is compared to a template and that the beat is rejected if it does not match, that if the QRS amplitudes are the same as the template amplitudes, the QRS amplitudes are used, and that 40 points are used to for a cross correlation and if they correlate, the points are

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used, and therefore analyzes a “noise” signal and discards noisy/uncorrelated signals if exceeds the threshold. In addition, Ambos averages the QRS amplitudes and pulsometric parameters (a standard of measurement for the pulse) such as the ST segment and X, Y, and Z, point by point data, as discussed in columns 4, 5, etc.

In the alternative for the analyzing the noise level (claim 54) and calculating the noise level, comparing it to a threshold, and excluding the current R-R if it exceeds the threshold (claim 56), Ambos discloses the claimed invention except for analyzing the noise level. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ECG system and method as taught by Ambos, with the analyzing of the noise level and calculating the noise level, comparing it to a threshold, and excluding the current R-R if it exceeds the threshold since it was known in the art that ECG systems and methods analyze the noise level and calculate the noise level, compare it to a threshold, and exclude the current R-R if it exceeds the threshold to determine if the signal is or is not noisy and if the signal should be used for processing since noisy signals may falsely indicate a serious heart condition or mask a serious heart condition.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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*Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 53-60 and 71-73 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6656125. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are narrower and meet the limitations of the broader application claims. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the patented claims the use a HR max and min, HRV, groups of consecutive premature beats, an atrial/ventricular fib/flutter, and a standard deviation of the average normal to normal R-R interval since it was known in the art that ECG systems and methods use this data to further accurately determine and predict future heart conditions.

#### ***Allowable Subject Matter***

Claims 61-70 are allowed upon correction of the claim objections.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko  
Primary Examiner  
Art Unit 3762

12/31/06

GRE  
December 31, 2006